Docket No.: 4614-0169PUS1

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Erik ANDERSEN et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

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Art Unit: N/A

For: STENT ASSEMBLY

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The PTO is requested to use the amended sheets/claims attached hereto (which correspond to Article 19 amendments or to claims attached to the International Preliminary Examination Report (Article 34)) during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Application No.: Not Yet Assigned Docket No.: 4614-0169PUS1

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KM/nl

Respectfully submitted,

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Attachment(s)

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5 NEW CLAIMS, 11 OCTOBER 2004

- 1. A stent assembly comprising a tubular stent, an external surface of which is provided with a fabric, <u>characterized in that</u> the fabric has been pre-formed into the shape of a tube, into which the stent has been placed in the unexpanded state of the stent, the fabric tube having an inner diameter which is smaller than the outer diameter of the stent when the tube is placed on the stent to achieve an inward gripping action of the fabric tube on the unexpanded stent.
- 2. A stent assembly according to claim 1, wherein the fabric tube has been manufactured with an inner diameter which is smaller than the outer diameter of the unexpanded stent.
 - 3. A stent assembly according to claim 1, wherien the fabric tube has been longitudinally folded to a smaller diameter than the outer diameter of the stent when fitted over the unexpanded stent.
 - 4. A stent assembly according to any of the preceding claims, wherein the fabric constitutes a reservoir to hold drugs.
- 5. A stent assembly according to any of the preceding claims, wherein the fabric is made from a filamentary material.
 - 6. A stent assembly according to claim 5, wherein the filamentary material includes at least one polymer.
- 7. A stent assembly according to claim 6, wherein the at least one polymer is selected from the group consisting of: polyurethane, polyamide, gelatine, silicone and agar.
 - 8. A stent according to any of claims 5-7 wherein the fabric is made from a multifilament yarn.
 - 9. A stent assembly according to any of the claims 5-7, wherein at least a portion of the fabric is produced by spinning of nanofibers.
 - 10. A stent assembly according to claim 9, wherein said portion is produced by electrospinning.

AMENDED SHEETS

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- 11. A stent assembly according to claim 9 or 10, wherein the diameter of the nanofibers is in the range of 2 to 4000 nanometers, such as in the range of 2 to 3000 nanometers.
- 5 12. A stent assembly according to any of claims 9-11, wherein the nanofibers are made from a polymer.
 - 13. A stent assembly according to claim 12, wherein the nanofibers are made from a material selected from the group consisting of: nylon, fluoropolymers, polyolefins, polyimides, and polyesters.
 - 14. A stent assembly according to any of the preceding claims, wherein the fabric has an openness which allows the fabric to serve as a reservoir for liquid-based drugs.
- 15. A stent assembly according to any of the preceding claims, wherein the tubular stent comprises an assembly of radially expandable, tubular elements aligned along a common longitudinal axis and successively joined together in pairs by respective sets of linking members.
- 20 16. A stent assembly according to claim 15, wherein each tubular element exists essentially of a strip forming a zigzag corrugation.
 - 17. A stent assembly according to any of the preceding claims, wherein the fabric completely covers the cylindrical external surface of the stent.
 - 18. A stent assembly according to any of the preceding claims, wherein the stent is crimped onto a balloon for expanding the stent.
- 19. A stent assembly according to any of the preceding claims, wherein the stent is auto-30 expandable.
 - 20. A stent assembly according to claim 19, wherein the stent is made essentially from a material selected from the group consisting of: stainless steel, Phynox®, and nitinol.
- 21. A stent assembly according to any of claims 1-18, wherein the stent is expandable by forced expansion, the stent being made essentially from a metallic material.
 - 22. A stent assembly according to claim 21, wherein the metallic material is selected from the group consisting of: tungsten, platinum, tantalum, gold, and stainless steel.

- 23. A method of manufacturing a stent assembly according to any of the preceding claims, comprising the steps of:
- manufacturing the stent;
- applying the fabric to the stent, characterized in that
- the fabric is preformed into the shape of a tube before the fabric is applied to the stent, the step of applying the fabric to the stent comprising placing the unexpanded stent into the fabric tube, the fabric tube having an inner diameter which is smaller than the outer diameter of the stent when the tube is placed on the stent to achieve an inward gripping action of the fabric tube on the unexpanded stent.

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- 24. A method according to claim 23, wherein the fabric tube is preformed with an inner diameter which is smaller than the outer diameter of the unexpanded stent.
- 25. A method according to claim 23, wherein the step of applying the fabric tube to the stent comprising longitudinally folding the fabric tube to a smaller diameter than the outer diameter of the unexpanded stent.
 - 26. A method according to any of claims 23-25, wherein the fabric is manufactured by spinning of nanofibers.

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- 27. A method according to claim 26, wherein the step of spinning comprises electrospinning.
- 28. A method according to claim 26 or 27, wherein the diameter of the nanofibers is in the range of 2 to 4000 nanometers.

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- 29. A method according to any of claims 26-28, wherein the step of spinning comprises feeding a first fiber-forming material into a nozzle for forming nanofibers by using a pressurized gas stream, and ejecting the first fiber-forming material from an exit orifice of the nozzle in the form of a plurality of strands of said first fiber-forming material that solidify and form said nanofibers.
- 30. A method according to any of claims 26-29, wherein the nanofibers are made from a polymer.
- 31. A method according to claim 30, wherein the nanofibers are made from a material selected from the group consisting of: nylon, fluoropolymers, polyolefins, polyimides, and polyesters.
- 32. A method according to any of claims 23-31, wherein the stent is manufactured from a hollow tube, in which a pattern of tubular elements and linking elements is formed.

33. A method according to any of claims 23-31, wherein the step of manufacturing the stent comprises rolling up of a sheet of material to form the tube, and securing adjoining edge portions of the sheet together.

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34. A method of preparing a stent assembly according to any of claims 1-22, comprising the step of providing a drug to the fabric.